

Notice of Allowability

Application No.

10/811,727

Applicant(s)

PFEIFFER ET AL.

Examiner

Rei-tsang Shiao, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on April 16, 2007.
2. ☒ The allowed claim(s) is/are 12-18, now are 1-7.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
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| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. This application claims benefit of the foreign applications:
FRANCE 00.08791 with a filing date 07/06/2000; and FRANCE PCT/FR01/02169 with a filing date 07/06/2001.
2. Amendment of claims 20, cancellation of claims 1-11 and 19 in the amendment filed on April 16, 2007, is acknowledged. Claims 12-18 and 20-23 are pending in the application.

Responses to Amendment/Arguments

3. Applicant's arguments regarding the rejection of claims 20 and 22-23 under 35 U.S.C. 102(a) or 102(e) over Guez et al. US 6,653,336 (or WO99/25374) filed on April 16, 2007, have been fully considered and they are not persuasive. Since Guez et al. (i.e., same assignee) disclose the same compound and its pharmaceutical composition comprising a diuretic indapamide, the rejection of claims 20 and 22-23 under 35 U.S.C. 102(a) or 102(e) is maintained. A side-by-side comparison disclosing distinctness between Guez et al. and the instant claims would obviate the rejection.
4. Applicant's arguments regarding the rejection of claims 12-18 and 20-23 under 35 U.S.C. 103(a) over Vincent et al. '214 in view of Guez et al. '336 or Brittan's publication filed on April 16, 2007, have been fully considered and they are persuasive, in part. Since the instant gamma crystalline form of the compound of formula (I) and their processes of making have not been found in Vincent et al. '214 or Guez et al. US '336, the rejection of claims 12-18 under 35 U.S.C. 103(a) has been

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withdrawn herein. However, the instant pharmaceutical compositions and methods of use still render obviousness of Vincent et al. '214 in view of Guez et al. '336 or Brittan's publication, the rejection of claims 20-23 under 35 U.S.C. 103(a) is maintained.

5. Applicant's arguments regarding the provisional rejection of claims 20-23 under the obviousness-type double patenting over Pfeiffer et al. co-pending application No. 11/052,489, or over Pfeiffer et al. co-pending application No. 10/792,355 in view of Brittain's publication, have been fully considered and they are not persuasive. The instant pharmaceutical compositions and methods of use still render obviousness of Pfeiffer et al. The provisional rejection of claims 20-23 under the obviousness-type double patenting over Pfeiffer et al. co-pending application No. 11/052,489, or over Pfeiffer et al. co-pending application No. 10/792,355 in view of Brittain's publication, is maintained.

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with G. Patrick Sage on July 12, 2007. The application has been amended as follows:

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In claim 12, after the last line (i.e.,

29.589	3.02	96	6.1
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insert

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Delete claims **20-23**

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

Claims 12-18 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to Gamma crystalline form of perindopril tert-butylamine salt. The closest reference is Vincent et al. US 4,914,214, which disclose Process for the industrial synthesis of perindopril. The difference between the reference and instant claims is that the instant gamma crystalline form of perindopril tert-butylamine salt has not been found. A suggestion for modification of above reference to obtain the instant crystalline form of formula (I) and their processes of making has not been found. Claims 12-18 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
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July 13, 2007